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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
1300 I STREET, NW
WASHINGTON, DC 20005

[REDACTED] EXAMINER

JOYNES, ROBERT M

ART UNIT	PAPER NUMBER
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/779,095	GUERET, JEAN-LOUIS	
	Examiner	Art Unit	
	Robert M. Joynes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 26 June 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,5-30 and 35-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,5-30 and 35-53 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>17 an 20</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' Request for Reconsideration filed on June 26, 2003 and Information Disclosure Statement filed on June 26, 2003 and August 15, 2003. Claims 1, 5-30 and 35-53 remain pending.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 6, 10, 11, 14-18, 21, 27, 28, 30, 36-39, 41, 43, 45, 47, 48 and 50-53 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolter et al. (US 5132115). Wolter teaches a transdermal skin patch comprising a backing layer, a drug reservoir layer, a support layer and an additional skin contacting adhesive layer (Col. 4, lines 36-46). The system is used for the local or systemic transdermal administration of drugs in human or veterinary medicine or in cosmetics (Col. 4, lines 59-62). The system comprises one or more active agents wherein the active agent can be one listed in the Specification (Col. 3, line 2 – Col. 4, line 35). The drug reservoir layer is a matrix with a drug wherein the matrix comprises a low or high, molecular, natural or synthetic material such polyacrylates, which swell upon contact with water (Col. 6, line 59 – Col. 7, line 4). The drug reservoir also contains suitable additives such as dissolving aids, softeners, stabilizers, fillers and enhancers (Col. 7, line 5-9). The backing layer is impermeable and comprises polymeric substances including polyethylene, polypropylene,

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polyethylene terephthalate and polyamides as well as metal sheets such as aluminum foil (Col. 7, lines 23-34). The support layer is made of a flexible support material such as paper, plastic, metal sheets or textile sheets (Col. 7, lines 62-67).

The limitations of Claims 1, 5, 6, 10, 11, 14-18, 21, 27, 28, 30, 36-39, 41, 43, 45, 47, 48 and 50-53 are all taught by the Wolter reference. Therefore, Claims 1, 5, 6, 10, 11, 14-18, 21, 27, 28, 30, 36-39, 41, 43, 45, 47, 48 and 50-53 are anticipated by the reference.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 7-9, 19, 20, 22-24, 29, 35, 40, 42 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolter in combination with Kim. The teachings of Wolter are discussed above. Wolter does not expressly teach the drug reservoir layer components contain a moisture-absorbing component nor does it teach multiple layers

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of drug reservoirs but the reference does teach the incorporation of multiple drugs in the reservoir. Wolter teaches some reservoir materials but teaches that any known reservoir system in the art can be used.

Kim et al. teaches a transdermal skin patch comprising a backing layer that is water impermeable, a multi-layer laminate of 2 to 5 adhesive layers wherein each layer has an active agent, an adhesive resin, a water absorptive agent and a lenitive agent and a liner (Col. 14, Claim 1). The adhesive resins of the adhesive layers of the patch include silicone polymers, natural or synthetic rubbers and acrylic polymers (Col. 5, line 52 – Col. 6, line 47). Water absorptive agents are also included in the adhesive layer. They include polymers, polyols and inorganic material, more specifically, polyvinyl alcohol, polyvinyl pyrrolidone, alginic acid, hyaluronic acid, cellulose, chitin, zinc oxide, calcium oxide, silica, kaolin talc and titanium dioxide (Col. 6, lines 48-67; Col. 7, lines 51-59). The water absorptive agents are presenting the patch in amounts of 0.1% to 40% by weight (Col. 6, lines 48-67). The actives include anti-inflammatory drugs such as salicylic acid, ibuprofen, naproxen, and piroxicam (Col. 7, lines 41-50). The adhesive layers are laminated to each other to form a multi-layer patch (See Examples 1-4). The patch further contains plasticizers, fillers, antioxidants and preservatives (Col. 7, lines 34-40).

Kim does not teach the exact concentration ranges for all of the recited ingredients.

While the reference does not teach the complete concentration range, differences in concentration will not support the patentability of subject matter

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encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to vary the amount of each ingredient in the patch composition. It would also be obvious to one of ordinary skill in the art to prepare a suitable drug reservoir layer as an adhesive layer with a particular active agent and a moisture-absorbing component present in the matrix. One of the named active agents in Wolter is diclofenac. Kim's transdermal system is taught to be suitable for diclofenac. Therefore, it would be obvious from the teachings of Wolter that one can implement a drug layer such as the one taught by Kim in the system of Wolter to delivery a known drug such as diclofenac with moisture absorbing agents.

One of ordinary skill in the art would have been motivated to do this to adjust dosage levels for the various hosts to receive treatment through the patch, which in turn, would vary the amount of other ingredients in the composition. One of ordinary skill would also be motivated to prepare a drug reservoir layer such as the layers taught by Kim to deliver active agents in a manner and with a material that is suitable for the particular active agent. One would be motivated to include a moisture-absorbing component in the drug matrix layer in order to adjust the moisture absorbing mature of the layer to regulate release of the drug from the layer.

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Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolter in combination with Jehan (GB 2307862). The teachings of Wolter are discussed above. Wolter does not expressly teach the use of magnetizable particles in the composition.

Jehan teaches the incorporation of magnetizable particles in a transdermal patch composition (Page 2). In one embodiment, copper and zinc are the particulate incorporated and when placed on the skin small electromagnetic impulses are generated (Page 3-4).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate magnetizable particles into a transdermal patch composition.

One of ordinary skill in the art would have been motivated to do this treat skeletal or muscular pain (Page 4 of Jehan).

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolter in combination with Gueret et al. (US 5026552, hereafter "Gueret"). The teachings of Wolter are discussed above. Wolter does not expressly teach that the layers are juxtaposed to each other with different active agents.

Gueret teaches a patch or mask comprising mesh support structure (Col. 3, lines 5-23), a gel containing an active agent (Col. 3, lines 24-66) and a support sheet (Col. 5, lines 26-37; Col. 8, lines 13-23)(Anticipating Claims 1, 15-18) wherein the support sheet can be permeable or impermeable (Col. 4, lines 41-57). Gueret further teaches that application of different gels, each including a different active agent may also be provided on the same sheet/mesh at different sites on the sheet/mesh (Col. 7, lines 15-20).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate different active agents in one patch system. It would also be obvious to place the layers or sections containing the different drugs juxtaposed to each other

One of ordinary skill in the art would have been motivated to do this to deliver two different drugs simultaneously to a host in need thereof.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolter in combination with Auguste et al. (US 6338839). The teachings of Wolter are discussed above. Wolter does not expressly teach the incorporation of polyamides as the inert fillers in the adhesive matrix.

Auguste teaches a skin composition wherein the filler included in the composition can be silica, talc and polyamides (Orgasol) (Col. 5, lines 4, 49-58).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to prepare an adhesive matrix layer for a transdermal device that includes conventional components, specifically polyamides as inert fillers.

One of ordinary skill in the art would have been motivated to do this to prepare a matrix with enhanced feel or to thicken the matrix or to aid in the binding or gelling of the matrix.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolter in combination with Gilchrest et al. (US 5962417). The teachings of Wolter are discussed above. Wolter does not expressly teach that the patch is applied to hair.

Gilchrest teaches a transdermal patch can be applied to the skin or hair follicles (Col. 9, lines 56-59)

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to apply a patch composition to the skin or hair of a host.

One of ordinary skill in the art would have been motivated to do this to deliver active agents to the most effective site on the host for treatment.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed June 26, 2003 have been fully considered but they are not persuasive. Applicants argue that the primary reference (Wolter) does not teach

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a composite structure wherein an adhesive layer is sandwiched between two non-adhesive layers. It is the position of the Examiner that the prior art does teach such a composition.

Wolter teaches a composite comprising a backing layer that is non-adhesive, a drug reservoir layer that is self-adhesive, a support layer that is non-adhesive and an additional skin contacting adhesive layer. The drug reservoir layer is a matrix with a drug wherein the matrix comprises a low or high, molecular, natural or synthetic material such polyacrylates, which swell upon contact with water (Col. 6, line 59 – Col. 7, line 4). Further, Wolter teaches that the reservoir layer is self-adhesive (Col. 8, lines 1-7). This reservoir layer is the layer that contains the active agent or drug. The backing layer is impermeable and comprises polymeric substances including polyethylene, polypropylene, polyethylene terephthalate and polyamides as well as metal sheets such as aluminum foil (Col. 7, lines 23-34). The support layer is made of a flexible support material such as paper, plastic, metal sheets or textile sheets (Col. 7, lines 62-67). Therefore, the prior art teaches a composite wherein the adhesive layer containing the drug is sandwiched between two non-adhesive layers. To that extent, applicants' arguments are unpersuasive.

All of applicants' arguments are based on the contention that Wolter does not teach a composite structure wherein an adhesive layer is sandwiched between two non-adhesive layers. Therefore, for the reasons stated above, all 103 rejections arguments are found unpersuasive as well.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joynes whose telephone number is (703) 308-8869. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Robert M. Joynes
Patent Examiner
Art Unit 1615
September 17, 2003


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600